1.0 PURPOSE

This policy provides guidance to Principal Investigators and research personnel for the development of protocol documents for clinical trials that are funded or sponsored by DAIDS.

2.0 SCOPE

This policy applies to all clinical trials funded or sponsored by the Division of AIDS (DAIDS) that are conducted outside of the DAIDS sponsored HIV/AIDS Clinical Trial Networks.

It does not apply to clinical trials developed within or in collaboration with the HIV/AIDS Clinical Trial Networks that utilize Network-specific templates for protocols and associated documents.

This policy can be superseded by specific terms of award included in Notice of Grant Awards, Statement of Work in NIAID contracts, or specific requirements identified in NIAID Program Announcements, Requests for Applications or Requests for Proposals.

3.0 BACKGROUND

A protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a clinical trial. The protocol document should provide unambiguous direction to promote consistent and reliable study implementation, conduct and analysis and facilitate participant safety throughout.

4.0 DEFINITIONS

See DAIDS glossary.

5.0 RESPONSIBILITIES

The Principal Investigator is responsible for ensuring that the protocol document developed by the team and submitted to the DAIDS for review and approval is complete and consistent, methodologically sound, and directs study conduct to be in accord with all applicable regulations, NIH and DAIDS Policy. Protocol documents for clinical trials that will be conducted in a single location must also reflect awareness of and compliance with local laws and regulations.

DAIDS Scientific Review Committees are responsible for the review, comment and final approval or disapproval of all clinical trials sponsored and/or funded by the DAIDS.

The DAIDS Medical Officer is responsible for review and written approval of the final version of the protocol which is required prior to implementation.

6.0 POLICY

The Clinical Trial Protocol should contain all essential information required to implement, plan and conduct a study and should be organized so as to allow ready access to relevant information.

The clinical trial protocol document must reflect awareness of and compliance with the following:

- All clinical trials sponsored or funded by the DAIDS must be designed and conducted in compliance with U.S. Code of Federal Regulations 45 CFR 46 and Subparts and the International Conference on Harmonisation, Good Clinical Practices.
- Clinical trials submitted to the FDA for review must be conducted in accordance with the applicable FDA regulations.
- All human subjects research sponsored or funded by DAIDS must comply with all applicable laws and regulations at clinical research site.
- The NIH, the NIAID, and the DAIDS have specific policy and guidance directing particular aspects of study development, implementation, monitoring, analysis and publication.

The DAIDS Guidance for Protocol Documents identifies requirements for protocol content for clinical trials, identifies other regulatory and guidance documents that should be consulted during protocol development, and specifies the level of detail that must be incorporated in the primary protocol document. It does not require that a specific format is utilized. This document is reviewed periodically and updated as necessary to maintain currency with accepted practices, policy, and regulations.

7.0 REFERENCES

U.S. Code of Federal Regulations: 45 CFR 46 and Subparts B, C, and D.

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline (GCP)

U.S. Code of Federal Regulations: 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 11

NIAID Clinical Terms of Award

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

Appendix 1 – DAIDS Protocol Guidance for Protocol Documents

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006